UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION This Document Relates To: All Actions	MDL No. 15-2666 (JNE/FLN) **JOINT RESPONSE BY NONPARTY VITAHEAT MEDICAL, LLC AND DEFENDANTS TO PLAINTIFFS' OBJECTION TO MAGISTRATE JUDGE'S DENIAL OF PLAINTIFFS' MOTION TO OVERRULE VITAHEAT'S RELEVANCE OBJECTION**

On March 6, 2017, Judge Noel issued an order sustaining third-party VitaHEAT Medical, LLC's relevance objection to Plaintiffs' subpoena. Judge Noel's order is reviewed under a deferential standard, whereby the order will be modified or set aside only if it is "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a); D. Minn. L.R. 72.2(a).[1] Plaintiffs' objection to the order fails to demonstrate any error of fact or law.

Judge Noel's order was well supported by both the record evidence and the case law. He relied on the product design evidence submitted by VitaHEAT and Defendants, including the declaration of Albert Van Duren. As Mr. Van Duren explains, the VitaHEAT UB3 system and Bair Hugger system employ fundamentally different technologies to warm

[1] "A finding is clearly erroneous when "although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Lisdahl v. Mayo Found.*, 633 F.3d 712, 717 (8th Cir. 2011) (quotation omitted). "A decision is contrary to law when it fails to apply or misapplies relevant statutes, case law or rules of procedure." *Knutson v. Blue Cross & Blue Shield of Minn.*, 254 F.R.D. 553, 556 (D. Minn. 2008) (quotation omitted).

patients: the VitaHEAT UB3 system employs *conductive* warming (*i.e.*, heat transferred by direct contact such as an electric heating pad), whereas the Bair Hugger system employs *convective* warming (*i.e.*, heat transferred by movement of warm air).

Plaintiffs offered no declaration or other scientific evidence to contradict Mr. Van Duren. Judge Noel also cited and followed the overwhelming body of case law in products liability cases holding that substantially different products like 3M's Bair Hugger system and VitaHEAT's UB3 system cannot, as a matter of law, qualify as feasible safer alternative designs. *Id.* at 2-3; *Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016) (plaintiff must show "the product in question could have been more safely designed, not that a different product was somehow safer"). Plaintiffs do not identify any Eighth Circuit decision to the contrary.

For these reasons, as well as the reasons set forth below, this Court should overrule Plaintiffs' objection to Judge Noel's order.

ARGUMENT

Under Rule 26(b)(1), a party may not conduct discovery that is irrelevant to the parties' claims or defenses. The amended Rule is consistent with longstanding Eighth Circuit law, which requires the proponent of the discovery to make a "threshold showing of relevance . . . before parties are required to open wide the doors of discovery," so as to limit "fishing expeditions in discovery." *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 380 (8th Cir. 1992). As Judge Noel correctly concluded, Plaintiffs failed to make that threshold showing. Plaintiffs' sole basis for asserting the relevance of the VitaHEAT's documents was that the VitaHEAT UB3 system is a "feasible safer alternative design" to the Bair

Hugger system. That assertion was both contrary to the evidence before the Court and the overwhelming weight of the case law.

I. The Evidence Strongly Supports Judge Noel's Factual Analysis.

The record evidence strongly supported Judge Noel's analysis. In the declaration submitted by VitaHEAT and Defendants, Mr. Van Duren explained that the Bair Hugger system's convective warming technology is fundamentally different from the VitaHEAT UB3 system's conductive warming technology. ECF No. 238, Van Duren Decl. ¶ 4. The Bair Hugger warming unit generates temperature-controlled warm air, which is then delivered into a blanket with small perforations. Heat transfer is accomplished through the gentle dispersion of warmed air through the small perforations in the Bair Hugger blanket across the patient's skin. *Id.*

By contrast, the VitaHEAT UB3 is an underbody mattress that uses conductive ink technology to transfer heat directly from the mattress to a patient's skin. *Id.* ¶¶ 5, 7. Heat is transferred through direct surface-to-surface contact. *Id.* As a result of this fundamental technological difference, the Bair Hugger system could not be modified to incorporate the VitaHEAT UB3's conductive warming technology, any more than the VitaHEAT UB3 could be modified to incorporate the Bair Hugger system's convective technology. *Id.* ¶ 6. Plaintiffs offered no scientific evidence – through an expert declaration or otherwise – to rebut Mr. Van Duren or to demonstrate that the conductive warming technology of the VitaHEAT UB3 system could be incorporated into the Bair Hugger system.[2]

[2] The positions Plaintiffs attempt to attribute to Mr. Van Duren are clearly rejected by him *in the very same documents Plaintiffs cite*. *See, e.g.*, ECF No. 221, Sacchet Decl. Ex. D

Plaintiffs argue that Judge Noel "disregarded facts" and arguments that Plaintiffs never presented in their motion papers. Those "facts" and arguments should not now be considered by the Court in reviewing Judge Noel's order. *Ridenour v. Boehringer Ingelheim Pharm., Inc.*, 679 F.3d 1062, 1067 (8th Cir. 2012) ("[Plaintiff] was required to present all of his arguments to the magistrate judge, lest they be waived."). Even if the Court considers Plaintiffs' improper presentation of new "facts" and arguments, they still do not demonstrate any error by Judge Noel.

First, Plaintiffs argue that Judge Noel clearly erred in concluding that the VitaHEAT UB3 and Bair Hugger system are "substantially different products" because (Plaintiffs say) "[t]he FDA cleared both UB3 and Bair Hugger as 'Thermal Regulation Systems[]' and found Augustine's HotDog is 'substantially equivalent' to Bair Hugger, and UB3 is 'substantially equivalent to HotDog.'" Pl. Obj. at 5.[3] Plaintiffs base their argument on a misunderstanding of substantial equivalence. Substantial equivalence does not mean that the devices employ the same kind of technology. As the FDA explains, a

(Van Duren describes as "Crazy Town" and "outrageous" viewpoints of *Augustine* that Plaintiffs falsely attribute to Van Duren).

[3] As Judge Noel noted, he previously denied Defendants' motion to compel Augustine to produce HotDog-related document because Plaintiffs had not taken the position that the HotDog was a safer alternative design to the Bair Hugger system – even though (like the VitaHEAT UB3) it is a conductive warming system. ECF No. 148 at 3. While Defendants' primary basis for seeking these documents was to demonstrate Augustine's bias and lack of credibility on scientific issues (*see* ECF No. 130 at 35), 3M did also cite the issue of alternative design. Defendants recognize that they were incorrect to make that argument at the time, because any product using conductive warming is substantially different from the Bair Hugger system and cannot qualify as a feasible safer alternative design.

medical device may be substantially equivalent to another device with "different technological characteristics" so long as it "has the same intended use" and is demonstrated to be "at least as safe and effective as the legally marketed device." *See* FDA, "Premarket Notification 510(k), online at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/. The Bair Hugger system, the VitaHEAT UB3, and the HotDog all share the purpose of "thermal regulation" – that is, patient warming. But, as courts have consistently concluded, the fact that a product shares a ***purpose*** with another product does not mean the product can legally qualify as a feasible safer alternative design. *See Massa v. Genentech Inc.*, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012); *Burks v. Abbott Labs.*, 2010 WL 1576779, at *4 (D. Minn. Apr. 20, 2010). Conductive products (*i.e.*, electric blanket- or pad-type products) such as the VitaHEAT UB3 and Augustine HotDog employ fundamentally different technologies from convective products (*i.e.*, products that use warm air) such as the Bair Hugger system.[4]

Second, Plaintiffs misrepresent the deposition testimony of Mr. Van Duren (a deposition that occurred on March 7, the day after Judge Noel's order). Plaintiffs falsely state that Mr. Van Duren's testimony "vitiates" his declaration. Pl. Obj. at 7. In fact, Mr.

[4] Plaintiffs also cite a statement from an article that "[u]nderbody resistive heating may be an alternative to forced-air warming." Pl. Opp. at 6-7. All this means is that one technology may serve the same purpose (patient warming) as another technology. A motorcycle and a car share the purpose of getting a person from point A to point B, but that does not make them feasible safer alternative designs. *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995).

Van Duren's testimony is perfectly consistent with his declaration. As the cited portions of his testimony make clear, Mr. Van Duren was responding to questions about the basic distinction between heat transfer via convection versus heat transfer via conduction:

> Q. You used the term "convective." What do you mean by "convective?"
>
> A. It's a mode of heat transfer that requires a fluid[5] to transfer the energy from one source to another, from a source to a target.
>
> Q. Okay. And you also mentioned conductive, and that is --
>
> A. That's the transfer of energy by direct contact between two surfaces of a different temperature.
>
> Q. You agree with me that the Bair Hugger does transfer some energy by direct contact; correct?
>
> A. Very little.
>
> Q. But it does transfer by direct contact. Yes?
>
> A. Yes.

ECF No. 268, Van Duren Dep. at 134:9-24.

This is a straightforward explanation of the physics of conductive and convective heat transfer. With any forced air warming device, there can be a tiny amount of conductive heat transfer when the warm blanket surface – solely warmed by the warmed air movement into the blanket – comes into direct contact with skin (provided the skin is cooler than the blanket surface). Convective transfer accounts for the vast and overwhelming majority of heat transfer, is the intended method of heat transfer, and any conductive transfer that occurs is trivial and incidental. There is no record evidence of heat generation from the

[5] Air is a "fluid" in the sense meant by Mr. Van Duren.

blanket itself. For conductive blankets or mattresses like the VitaHEAT UB3, there can be a tiny amount of convective heat transfer if there are areas where the blanket is not in direct contact with the skin and the blanket heats the air in between its surface and the skin. However, conduction accounts for the vast majority of heat transfer, is the intended method of heat transfer, and any convective transfer that occurs is trivial and incidental.

Mr. Van Duren's explanation of the basic physics of heat transfer does not contradict his declaration, and does not change the fact that a conductive device is substantially (indeed, fundamentally) different from a convective device.[6]

II. The Overwhelming Weight of Case Law Also Supports Judge Noel's Order.

Plaintiffs are entirely wrong to argue that Judge Noel's order is contrary to law. Judge Noel's order was consistent with the overwhelming weight of case law in this District and other jurisdictions.

Plaintiffs are wrong that a substantially different *product* can qualify as a feasible safer alternative design to the defendant's product so long as it is used for the same general purpose, is equally effective, and is (allegedly) safer. Case law holds that a substantially different product cannot qualify as a feasible safer alternative design, even if they share the same purpose. In the words of Judge Tunheim, plaintiffs "appear to confuse the existence of an alternative 'design' with an alternative 'product.'" *Burks*, 2010 WL 1576779 at *4 (concluding on defendant's motion to dismiss that liquid infant formula is not an alternative design for powder infant formula and noting that plaintiffs "appear to confuse the existence

[6] Plaintiffs cited Mr. Van Duren's testimony in a letter requesting leave to file a motion for reconsideration of Judge Noel's order. The Court denied leave. ECF No. 282.

of an alternative 'design' with an alternative 'product'"). As noted above, other courts also have repeatedly concluded that a plaintiff "cannot demonstrate the existence of a safer alternative design by pointing to a substantially different product, even when the other product has the *same general purpose* as the allegedly defective product." *Massa*, 2012 WL 956192 at *7 (emphasis added; internal quotation omitted). The plaintiff must show that "the *product in question* could have been more safely designed, not that a different product was somehow safer." *Tersigni*, 817 F.3d at 368 (emphasis added).[7]

[7] *See also Theriot v. Danek Med.*, 168 F.3d 253, 255-56 (5th Cir. 1999) (concluding that another company's device without a pedicle screw was not an alternative design to the defendant's device with a pedicle screw); *Hosford v. BRK Brands*, 2016 WL 4417256, at *4-5 (Ala. Aug. 19, 2016) (holding as a matter of law that the dual-sensor smoke alarm design put forth by the plaintiff was a design for a "different product altogether," rather than an alternative design for an ionization smoke alarm, even though both were sold for the purpose of detecting smoke); *Hilaire v. DeWalt Indus.*, 54 F. Supp. 3d 223, 248-49 (E.D.N.Y. 2014) (concluding that even though they both cut wood, a trap saw is an "entirely different device" from a table saw, and therefore cannot be an alternative design); *McCarthy v. Danek Med.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999) (alternative surgical methods for addressing spinal fusion, as compared to alternative designs for fixation devices, were not alternative designs for the purposes of a design-defect action); *Brockert v. Wyeth*, 287 S.W.3d 760, 762, 769-71 (Tex. App. Ct. 2009) (Premarin was not an alternative design to Prempro but a different product, even though they had the same purpose of treating menopausal systems); *Clanton v. 3M Co.*, No. 251-12-970 (Miss. Cir. Ct. July 1, 2014), slip op. at *5 (ECF No. 239-2) (rejecting plaintiff's position that non-disposable elastomeric mask was an alternative design for 3M's disposable mask because the elastomeric mask was an "entirely different product"); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) ("[A]n allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of design defect."); *Michael v. Wyeth, LLC*, 2011 WL 2150112, at *11 (W.D.W.Va. May 25, 2011) ("an alternative design must not be an altogether essentially different product"); *Pinello v. Andreas Stihl Ag.*, 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011) (plaintiff's contention that an "entirely different product" could have been used did not create a dispute of material fact as to whether there was an alternative design); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895 (E.D. Va. 2010) ("[A]n alternative design is not reasonable if it alters a fundamental and necessary characteristic

Plaintiffs argue that Judge Noel and the long line of cases he followed disregard that "a safer design alternative [may be] implemented in other products." Pl. Obj. at 10. Not so. *Of course* a plaintiff can point to a similar product that incorporates an additional safety feature, and then demonstrate that the defendant's product can also be reengineered to incorporate that additional feature. Judge Noel recognized this in footnote 2 of his Order. The point is that a plaintiff does not carry its burden by identifying a *different product* that employs a fundamentally *different type of technology*, and argues that the defendant should ditch its current technology in favor of that different technology because it is allegedly safer. That is the rule recognized by Judge Noel and a multitude of other cases.

In sum, overwhelming case authority holds that an alternative design must be a feasible *modification* to the defendant's product, not a different product that employs a fundamentally different technology to address the same (or similar) clinical purpose. Plaintiffs' argument that the Bair Hugger system should incorporate VitaHEAT's conductive warming technology, rather than convective warming, is not an argument that the Bair Hugger system should have been safer. Rather, it is an improper argument that the Bair Hugger system should have been a different product. *See Massa*, 2012 WL 956192, at *7 ("Massa's argument that 'Raptiva could have been formulated with a number of alternative underlying compounds' is not an argument that Raptiva should have been safer; it is an argument that Raptiva should have been a different product.").

---

of the product."); *Kimball v. RJ Reynolds*, 2006 WL 1148506, at *3 (W.D. Wash Apr. 26, 2006) (a plaintiff "cannot point to an entirely different product as an alternative design").

A. None of Plaintiffs' Cases Supports Their Position.

Plaintiffs cite a handful of cases in support of their view that a substantially different product can be a feasible safer alternative design. None of them is a controlling case from the Eighth Circuit, and none in fact supports Plaintiffs' view.

First, in *In re Mentor Corp. Obtape Transoburator Sling Prods. Liab. Litig.*, 2010 WL 234797 (M.D. Ga. Jan. 14, 2010), relevance was not even disputed. The plaintiffs subpoenaed R&D documents from a third party, Ethicon, on the basis that Ethicon's product (TVT) was a safer alternative design to Mentor's vaginal mesh product ("ObTape"). Mentor admitted the relevance of the discovery: the court noted that "Ethicon acknowledges that the design of TVT was an alternative design to ObTape." *Id.* at *2. Here, by contrast, 3M presented uncontroverted evidence that the VitaHEAT UB3 is not a feasible safer alternative design to the Bair Hugger system.

Second, in *Oldenburg v. Gymboree Corp.*, No. 12-cv-71, 2013 WL 6196970 (D. Minn. Nov. 27, 2013), the defendants did not dispute that alternative shirt fabrics (such as flame-retardant cotton) could be incorporated into their shirts. Nor did the court discuss the threshold legal standard for when a different product may qualify as a feasible safer alternative design.

Third, in *Block v. Toyota Mot. Corp.*, 5 F. Supp. 3d 1047 (D. Minn. 2014), the design modification proposed by the plaintiffs to address the alleged risk of sudden acceleration in the 1996 model Toyota Camry had been implemented in the 2000 model Camry. *Id.* at 1067. The plaintiffs did not attempt to rely on a substantially different

product (like a motorcycle or truck) as an alternative design, but rather an updated version of the same product.

Fourth, *Standard Fire Ins. Co. v. Broan Nutone, LLC*, 2008 WL 5560882 (S.D. Miss. July 1, 2008), is similarly unhelpful to Plaintiffs. Standard alleged that a fire broke out at its insured's home because the electric bathroom ventilation fan manufactured by Broan did not include an adequate thermal protection device. Standard's expert pointed to a major competitor of Broan that utilized thermal protective devices in its electric fans. *Id.* at *2. The court denied Broan's motion to exclude the expert's opinion, because Broan had submitted no evidence that incorporating a thermal protective device would destroy its fans' "utility, usefulness, practicability, and desirability." *Id.* at *5. In sum, plaintiffs' position was that an *additional* feature could be *incorporated into* Broan's products to make them safer, and Braun presented no evidence to the contrary.

B. Judge Noel Correctly Decided Not to Defer the Issue of Relevance Until Summary Judgment.

Judge Noel also did not err in rejecting Plaintiffs' request to defer the legal question of whether the VitaHEAT UB3 can qualify as a feasible safer alternative design until summary judgment.[8] Whether a product can legally qualify as a safer alternative feasible design is a *threshold* question for whether a design defect claim can proceed, and therefore whether discovery concerning that alternative product should occur at all. Courts

[8] In *Burks*, 2010 WL 1576779, Judge Tunheim allowed discovery despite his conclusion as a matter of law that "liquid infant formula is a different product entirely than powdered infant formula." Allowing discovery on legally insufficient claims would today be inconsistent with the relevance and proportionality standards of amended Rule 26(b)(1).

frequently dismiss design defect claims that identify a different product – including a different product also sold by the defendant – as a safer alternative feasible design. *See, e.g.*, *Massa*, 2012 WL 956192, at *7; *Bertini v. Smith & Nephew, Inc.* 2013 WL 6332684 (E.D.N.Y. July 15, 2013) (granting motion to dismiss because plaintiff failed to plead facts to plausibly suggest that it was feasible to design the device used in their cases in a safer manner; it was not enough to allege that defendant sold other versions of the R3 liner that were less dangerous than the one used in plaintiff's surgery"); *Salvio v. Amgen Inc.*, 2012 WL 517446 (W.D. Pa. Feb. 15, 2013) (granting a motion to dismiss where plaintiff alleged that defendant should have sold alternative drugs to Enbrel).

Based on the foregoing case law, it is a ***certainty*** that Plaintiffs will not be able to offer the VitaHEAT UB3 at trial as a safer alternative feasible design to the Bair Hugger system. The Court's time, the parties' times, and VitaHEAT's time should not be wasted with irrelevant discovery. (That is particularly so now, as the deadline for fact discovery on general causation passed on March 20.) For all these reasons, Judge Noel correctly rejected Plaintiffs' call to evade the legal threshold requirements and allow discovery.

CONCLUSION

The unrebutted record evidence demonstrates that VitaHEAT UB3 employs fundamentally different warming technology from the Bair Hugger system. Consistent with overwhelming case authority, Judge Noel correctly concluded that the VitaHEAT UB3 system could not, as a matter of law, be a feasible safer alternative design to the Bair Hugger system, and therefore was not relevant. Plaintiffs' objection to Judge Noel's order should be overruled.

Dated: April 3, 2017

Respectfully submitted,

*s/*Deborah E. Lewis

Deborah E. Lewis (#0397922)
Attorney for Non-Party
VitaHEAT Medical, LLC
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
T: (612) 343-3200 F: (612) 343-3205
dlewis@blackwellburke.com

Dated: April 3, 2017

Respectfully submitted,

*s/*Benjamin W. Hulse

Jerry W. Blackwell (#186867)
Benjamin W. Hulse (#0390952)
Mary S. Young (#0392781)
Attorneys for Defendants 3M Company and Arizant Healthcare Inc.
BLACKWELL BURKE P.A.
431 South Seventh Street, Suite 2500
Minneapolis, MN 55415
T: (612) 343-3200 F: (612) 343-3205
blackwell@blackwellburke.com
bhulse@blackwellburke.com
myoung@blackwellburke.com

Bridget M. Ahmann (#016611x)
Attorney for Defendants 3M Company and Arizant Healthcare Inc.
FAEGRE BAKER DANIELS LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402
T: (612) 766-7000 F: (612) 766-1600
bridget.ahmann@faegrebd.com